THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte GARY E. STRIKER, LILIANE J. STRIKER
and EMMANUEL PETEN

_____

Appeal No. 95-4471
Application No. 07/963,475[1]

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH, and ROBINSON, Administrative Patent Judges.
ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 - 16, which are all of the claims pending in this application. An understanding of the invention can be derived from a reading of claim 1, which is reproduced below:

[1] Application for patent filed October 20, 1992.

1. A diagnostic method comprising the steps of

(i) obtaining a sample of tissue from an organism by biopsy, wherein said tissue is subject to a fibrosing condition; then

(ii) isolating by microdissection an intact subsegment of said sample, which subsegment corresponds to a basic organizational structure of said tissue;

(iii) subjecting mRNA from said subsegment to reverse transcription to obtain cDNA molecules; and thereafter

(iv) bringing said cDNA molecules into contact with PCR primers under conditions such that a subpopulation of said cDNA molecules undergoes amplification, wherein cDNAs of said subpopulation encode protein molecules that are involved in basement membrane-synthetic and -degradative pathways related to said fibrosing condition; and

(v) analyzing said amplified subpopulation, whereby mRNA levels corresponding to said amplified subpopulation are monitored and a diagnosis is effected therefrom.

No references are relied upon by the examiner.

Grounds of Rejection

Claims 1-16 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure.

We reverse.

Background

The applicants' invention, as described at page 6 of the specification, is directed to a diagnostic method for fibrotic disease which employs a series of steps wherein discrete regions of organ tissue are examined for abnormalities in extracellular matrix (ECM) synthesis and degradation. The described steps include tissue biopsy, microdissection, reverse transcription, and polymerase chain reaction (PCR). The biopsy and microdissection are said to serve to parse out particular tissues for study and the reverse transcription and PCR serve to amplify molecules available on in trace amounts in the dissected tissue. The method is said to overcome obstacles previously encountered in the diagnosis of fibrotic disease.

The Rejection under 35 U.S.C. § 112, first paragraph

Claim 1-16 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure.

In setting forth the basis of this rejection, the examiner states (Answer, page 8):

> Thus, in view of the generic scope of the claim, disclosure of only specific examples, lack of specific guidance as to how to practice the broadly claimed invention and unpredictability due to the lack of understanding of the molecular basis of fibrotic disease, it would require undue experimentation to practice the claimed inventions.

In explaining the need for undue experimentation to practice the invention, the examiner states (Answer, page 5):

> (1) It would require an undue amount of experimentation to determine whether or not a gene falls within the claimed functional limitations and (2) even if a gene were shown to fall within the functional limitations it would require undue experimentation to determine whether it was functional in the claimed invention, that is, the gene has aberrant expression which is correlated with the presence of a fibrotic disease.

In addressing the sufficiency of the guidance provided by the specification the examiner states (Supp. Answer, page 2):

> The specification offers no guidance as to which of the myriad genes within the scope of these claims will function and which will not.

The examiner has conceded that the disclosure is at least enabled for those cDNAs and related proteins specifically exemplified by the specification. (Suppl. Answer, page 1). However, the examiner reads the claims as encompassing more than the use of these cDNAs. Thus, it is this aspect of the claimed method which the examiner considers to lack sufficient enabling support in the disclosure.

It would appear from the examiner's explanation of the rejection that it would be necessary to identify all, or at least a reasonable number, of other cDNAs, and related proteins, in order to enable the present claims within the meaning of 35 U.S.C. § 112, first paragraph. We do not agree. The steps of the claimed diagnostic method are clear. While the claims may encompass the use of ECM related PCR primers, and cDNAs of

proteins not specifically exemplified or identified, the claims do require that both the primers and proteins are known to be "related to said fibrotic condition."

To the extent that the examiner's rejection is premised on a position that appellants must teach how to find other proteins and related cDNAs, we simply note that the claims are directed to a method of diagnosis of a fibrotic disease and not to a method of identifying proteins related to the disease condition. There is no need to look for additional cDNAs or proteins, since the claims require only the use of those already known and shown to be related to the fibrosing condition. It would be expected that, as studies of fibrotic disease progress, other proteins related to the disease condition will be identified or discovered. However, the examiner has provided no reason why the diagnostic method, presently claimed, could not be readily modified to make use of such cDNAs and related proteins.

The examiner bears the initial burden of providing reasons for doubting the objective truth of the statements made by applicant as to the scope of enablement. In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971). On the record before us, we conclude that the examiner has not established a reasonable basis for questioning the sufficiency of the supporting specification with regard to the claimed method of diagnosis.

The rejection under 35 U.S.C. § 112, first paragraph is reversed.

SUMMARY

To summarize, the decision of the examiner to reject claims 1-16 under 35 U.S.C. § 112, first paragraph, is reversed.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	)	
WILLIAM F. SMITH Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
DOUGLAS W. ROBINSON Administrative Patent Judge	)	

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